

NHGRI IRB Checklist: Triennial Review of Protocols *(Include 1 copy with submission)*

Principal Investigator: _____

Protocol Number: _____ Title: _____

RENEWAL AFTER THREE YEARS (*original + 25 stapled copies*)

- ☐ Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- ☐ Decision memo from DEC regarding NIH employee conflicts of interest
- ☐ Cover memo addressing a) adverse events and protocol deviations over the past year; b) any “yes” responses to questions on 1195-1; c) amendments made within the last year; d) reason(s) for continuing the study; and e) currently proposed changes in protocol or consent form
- ☐ Table of contents, listing protocol and any appendices, recruitment materials, and consent forms
- ☐ Rewritten protocol:
 - ☐ Background section of protocol should address the following: a) protocol progress and key findings (including publication citations); b) changes in the field/new publications that have an impact on future direction; and c) description of new approaches
 - ☐ In addition, protocol should be revised/updated in all appropriate sections
- ☐ Ongoing Research Participant Enrollment Report
- ☐ Up-to-date consent form(s)
- ☐ Memo to Branch Chief responding point-by-point to SRC review
- ☐ SRC review
- ☐ Previous year’s IRB minutes for protocol

Materials for full IRB review must be submitted to Peggy McKoy, Bldg. 10, CRC/6-3340, by noon on the due date, or they may be reviewed at a later meeting. (See NHGRI IRB Calendar.)

For questions regarding the checklist or submissions, please contact:

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IRB forms and templates can be found at <http://www.genome.gov/10005807>

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